DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION
DRUG TESTING ADVISORY BOARD

December 7-8, 2004

The Drug Testing Advisory Board was convened for its meeting at 8:30 a.m. on December 7, 2004, at the Residence Inn, 7335 Wisconsin Ave., Bethesda, Maryland.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on December 7 from 8:30 a.m. to 9:30 a.m. The meeting was closed to the public on December 7 from 9:30 a.m. until adjournment on December 8 at noon to develop the analytical and administrative policies for the final revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Board members present:

Robert Stephenson II, Chairman
Dr. Alberto Gutierrez
Ann Marie Gordon
Patricia Pizzo
Dr. David Kuntz
Dr. George Jackson
Dr. William Reid
Dr. Matthew Slawson
Dr. Sue Brown
Dr. Frederick Fochtman

Executive Secretary present:

Dr. Donna Bush, Division of Workplace Programs (DWP), CSAP

Others present for all or a portion of the meeting were:

Dr. Walter Vogl, DWP, CSAP
Charles LoDico, DWP, CSAP
Ron Flegel, DWP, CSAP
Dr. John Mitchell, RTI International
Dr. Mike Baylor, RTI International
Dr. Craig Sutheimer, RTI International
Susan Crumpton, RTI International
George Ellis, Department of Transportation (DOT)

Dr. Yale Caplan, DOT Consultant
Tim McCune, Nuclear Regulatory Commission (NRC)

TOPICS DISCUSSED IN OPEN SESSION

Note: The transcript of the open session (including the handouts) is available on the Internet at: http://workplace.samhsa.gov

Opening Remarks

Dr. Bush introduced the four new members of the DTAB. They are Dr. Alberto Gutierrez (Food and Drug Administration), Ann Marie Gordon (Washington State Toxicology Laboratory), Dr. David Kuntz (Northwest Toxicology Laboratory), and Patricia Pizzo (Kroll Laboratory Specialists). She gave a brief summary of their backgrounds.

HHS Update

Dr. Bush gave a presentation on the revised Mandatory Guidelines that were implemented on November 1, 2004. The presentation focused on the following areas: the criteria/definitions used for determining if a specimen is adulterated, substituted, dilute, or invalid; the testing requirements a laboratory must use to report a specimen as adulterated, substituted, dilute, or invalid; the testing requirements for several different adulterants; the changes made in the HHS Specimen Collection Handbook and Medical Review Officer Manual to include the policies on specimen validity testing; and the National Laboratory Certification Program activities during the past several months to ensure that the HHS-certified laboratories were prepared to begin specimen validity testing on all Federal agency specimens.

DOT Update

Mr. Ellis (DOT) stated that DOT has a series of ongoing projects. First, DOT is planning to publish an employee guide for use by its operating administrations and by DOT regulated employers. There will also be an employer's guide that will provide an overview of the substance abuse prevention process and DOT's expectations on safety and the implementation of the DOT regulations.

Second, DOT will be publishing a new Medical Review Officer guide. Since DOT's regulations are different than those for Federal agencies, DOT cannot use HHS' Medical Review Officer Manual.

Lastly, DOT issued an Interim Final (IF) rule on November 9th to link the DOT drug testing program with HHS' recent implementation of urine specimen validity testing. The new IF rule was effective on November 9. There was one major difference, DOT specimen validity testing remained authorized but not mandatory for its regulated employers. If an employer chooses to have specimen validity tests conducted on its specimens, the testing must adhere to the HHS Guidelines. For laboratories, we removed any inconsistent reporting procedures

established by the previous May 2003 rule. However, DOT did require laboratories to report the quantitative values for creatinine concentration and specific gravity on all dilute specimens to MROs to ensure that MROs can implement the DOT's requirements for MROs in a correct and timely manner. The IF rule was implemented pending an upcoming notice of proposed rulemaking where DOT will formally request public comment and implement the urine specimen validity testing requirements.

NRC Update

Mr. McCune (NRC) stated that a revised 10 CFR Part 26, the NRC Fitness for Duty rule, is currently in the formulation stage and will be distributed for internal concurrence on January 5th. He expects to forward the complete package to the commissioners for their review by June 2005. The NRC incorporated specimen validity testing into the rule and closely followed the HHS Guidelines in that area. The rule also includes a fatigue aspect, primarily from the perspective of security, but also for our reactor operators. At the NRC, fitness for duty also means that employees must report to work in a status that they can achieve their job from an adequate sleep perspective.

The second rulemaking initiative the NRC is developing is for non-reactor licensees. Part 26 covers licensees that operate nuclear reactors. There is a second major class of licensees for fuel production facilities that make fuel for our reactors as well as cores for the Office of Naval Reactors in the Department of Defense. This rulemaking process has just started and the requirements will mostly be very similar to those in the current Part 26.

The NRC has also created a database that contains all the fitness for duty testing data from the 188 reactor licensees. The database will be used to track trends by licensee, geographical area, job specialty, etc. This approach will help the NRC to determine whether or not there are any patterns or issues that need to be addressed separately. The NRC also plans to share the database information with HHS.

Public Comments

Dr. Steven Soifer (International Paruresis Association) emphasized the importance of getting the alternative specimen testing procedures in place because people with paruresis are unable to provide urine specimens when required. He suggested that the Department issue an interim rule to allow alternative specimen testing as soon as possible until the final Guidelines can be implemented.

Ken Kunsman (OraSure) thanked the Board for its hard work and for giving the industry representatives an opportunity to provide input for the development of the proposed policies for testing alternative specimens.

The open session ended at 9:30 A.M.

TOPICS DISCUSSED IN CLOSED SESSION

The Board approved the Minutes for the September 14 – 15 meeting.

The Board discussed the public comments submitted regarding the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Program (69 FR 19673) and began developing recommendations for the Department to use in preparing the final revisions to the Guidelines.

Adjournment

The meeting adjourned at noon on December 8.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

/signed/

Donna M. Bush, Ph.D., D-ABFT
Executive Secretary, DTAB

/signed/

Robert L. Stephenson II, M.P.H.
Chairman, DTAB

These minutes will be formally considered by the Board at its next meeting, and any corrections or notations will be incorporated in the minutes of that meeting.